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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,381	04/19/2006	Shrenik K. Shah	21537YP	1854
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 08/02/2007		EXAMINER HAVLIN, ROBERT H	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 08/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/576,381

Applicant(s)

SHAH ET AL.

Examiner

Robert Havlin

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1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☒ Claim(s) 1-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### DETAILED ACTION

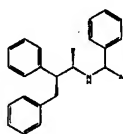
**Status of the claims:** Claims 1-10 and 16-20 are currently pending. At filing claim 5 was amended, claims 11-15 were cancelled, and claims 16-20 were added.

**Priority:** This application is a 371 of PCT/US04/35846 (10/27/2004) which claims benefit of 60/515,705 (10/30/2003).

**IDS:** The IDS dated 6/22/06 has been considered.

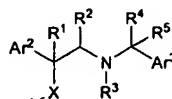
### Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-10, in part, drawn to a

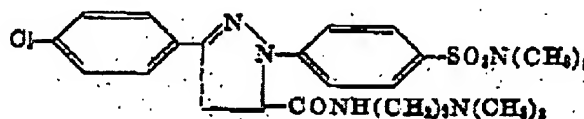


product with the core formula ) in the reply filed on 5/15/2007 is acknowledged.

The traversal is on the ground(s) that unity of invention exists. This is not found persuasive because the only common technical feature linking the claims is C-C-N-C as



described by the formula I of claim 1, specifically wherein every one of the variable groups can have chemically diverse definitions which would potentially result in non-obvious variants. Thus, the only discernable legitimate technical feature linking the claims is C-C-N-C as previously stated. Furthermore, the reference US 3,753,978



teaches the compound:

**EXAMPLE 4**

which does have a

C-C-N-C structure in it, contrary to the statements in the response to the requirement for restriction. In addition, the references cited in the following rejections also include this

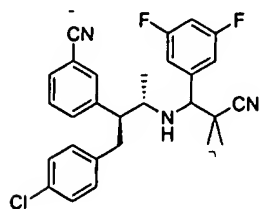
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same core structure further exemplifying the lack of a contribution over the prior art.

Therefore, the common technical feature linking the claims is not a contribution over the prior art and thus the application lacks a special technical feature. Furthermore, there is not a significant structural element shared by all of the alternatives since C-C-N-C would not be an art recognized common structural element nor do all of the compounds belong to a recognized class of chemical compounds.

The requirement is still deemed proper and is therefore made FINAL.

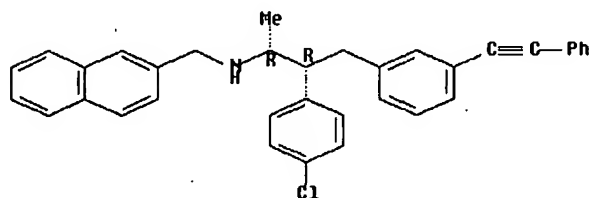
Applicant also elected the following species (reading on claims 1-7 and 9-15):



The following prior art references further support the restriction requirement since they contain compounds which would anticipate or render obvious the claimed subject matter if the requirement for restriction was not imposed.

For example:

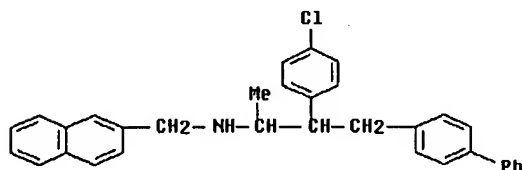
**Iwasawa et al.** (US 5,849,747) teaches a genus of pharmaceutical agents for inhibiting an enzyme including the specific example of (reference example 3, col. 70):



and

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**Nomoto et al.** (US 5,488,149) teaches pharmaceutical agents to inhibit the enzyme squalene synthase including the specific compound (reference example 2, col. 99):



Since the examiner did not find prior art anticipating or rendering obvious the elected group, the examiner has rejoined the method claims 16-20 within the scope of the elected group.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing

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many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

*(1) The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to a method of treating a disease mediated by the Cannabinoid-1 receptor and obesity in humans. Thus, the claims taken together with the specification imply that merely affecting the Cannabinoid receptor is sufficient to treat diseases which may be only peripherally related to the receptor's activity.

*(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

The state of the art in treating obesity with CB-1 antagonists is highly unpredictable. The teachings in Pagotto et al. (*Lancet*, 2005, v. 365, p. 1363-1364) describe the current state of the art as having a few existing drugs for the treatment of obesity and those only achieve a slight weight loss in the short term. Furthermore, the reference teaches that the existing drugs have other risk factors, which may prevent successful treatment of disease. Additionally, the article concludes that the mechanism of pharmaceutical treatment of obesity with CB-1 antagonist drugs has "unknown modes of action".

*(5) The relative skill of those in the art:*

The skill of those in the art is average for pharmaceutical development.

*(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

The specification has provided guidance for CB-1 binding assays to determine whether the compounds of the invention have any effect on the CB-1 receptor.

However, the specification does not provide any working examples demonstrating the compounds treating obesity or guidance as to how to perform the claimed methods.

*(8) The quantity of experimentation necessary:*

Considering the state of the art as discussed by the references above, particularly with regards to treating obesity and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

#### ***Claim Objections***

4. Claims 1-10 and 16-20 are objected to for reading on non-elected subject matter.

#### ***Conclusion***

Claims 16-20 are rejected. All pending claims are objected to.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.


If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Havlin  
Examiner

RH



KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER